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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,426	05/08/2001	Florence Bordon-Pallicr	146,1364	4261

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YAEN, CHRISTOPHER H

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 06/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/831,426	BORDON-PALLIER ET AL.
	Examiner	Art Unit
	Christopher H Yaen	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 March 2003 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14, 17 and 18 is/are pending in the application.
4a) Of the above claim(s) 4-11 and 14 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 12, 13, 17 and 18 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in Paper No. 18 is acknowledged.

The traversal is on the ground(s) that the lack of unity is improper because the different inventions have the same corresponding technical feature. This is not found persuasive because the different inventions refer to different sequences that correspond to different DNA sequence that encode different proteins. Because the nucleotide sequences encode different proteins, they cannot possibly be the same protein otherwise the proteins claimed would be have the same sequence identification numbers.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-14, 17-18 are pending, claims 4-11, and 14 are withdrawn from further consideration as being drawn to a non-elected invention, and claim 15-16 are canceled as per preliminary amendment. Applicant is reminded to cancel all claims drawn to non-elected inventions.
3. Therefore, claims 1-3, 12-13, and 17-18 are examined on the merits.

Claim Objections

4. Claims 1-3 and 12-13 are objected to because of the following informalities: The claims define the scope of an invention and must particularly point out and distinctly claim the invention, and must be a single sentence starting "I (We) claim:" or "What is claimed is:" Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3 and 13, as written, do not sufficiently distinguish over nucleic acids and cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page [insert page number] of specification. See MPEP 2105.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-3, 12-13 and 17-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claimed utility for the hTFIIIA nucleotide is for the diagnosis and identification of hereditary diseases such as cancer or any other disease resulting from abnormal transcription control. Additional usages for the hTFIIIA nucleotide sequence is for the

study of abnormalities in the transcription of genes. However, neither the specification nor any art of record teaches the specific role of hTFIIIA in the course of a disease such as cancer. Furthermore, the specification has not taught how this transcription factor is affected during the progression of a disease. Instead, the applicant has essentially provided a starting point from which further studies into the role hTFIIIA has in disease associated with transcription factors. The specification specifically states that the gene *“probably plays an important role in the initiation of the transcription of the 5S ribosomal RNA gene, and in maintaining the stability of the transcription of other genes involved in control function”* (see page 15), indicating that the function of hTFIIIA has not been clearly delineated. As such, the applicant has not established at the time of filing a clear mechanism of action for the hTFIIIA, and the claimed utilities are based on unsupported assertions. Fujiwara *et al* (EP 0704526A1) clearly states that although attempts have been made, “little is known about hTFIIIA” (see page 2). Because the claimed invention has not been clearly defined or established, the hTFIIIA nucleotide sequence as claimed, cannot be specifically associated with a specific disease or condition, and therefore the utility established is not specific or substantial for the claimed nucleotide.

Claims 1-3, 12-13, and 17-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph

9. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of treating a disease linked to transcriptional control disorders, wherein the disease is cancer. The art teaches that cancer is a rather unpredictable and difficult disease to treat, where many factors, such as testing, cell lines used and molecular targets must be determined and defined for in order for a therapeutic agent can be fully adapted as a potential therapeutic agent (see Kohler *et al* In Vivo 1998, Jan-Feb;12(1):35-41, Schirrmacher V Int Arch Allergy Immunol 1995 Dec;108(4):340-344; Balis FM Oncologist 1998;3(4):V; and Dermer GB Bio/Technology 1994;12:320). Furthermore, Fujiwara *et al* (EP 0704526A1) states that little is known about the hTFIIIA (see page 2). The instant specification has prophetically stated that the instant invention can be used in the treatment of diseases associated with transcriptional control disorders, such as cancer. However, the specification has not specifically taught the addition or elimination of hTFIIIA from cells and the effects such a process would have on the progression of a disease state. Because there is a lack of working examples provided in the specification, and because there is a great deal of unpredictability associated with the field of cancer treatment, one of skill in the art would essentially be forced into undue experimentation to practice the instant invention. The specification has not taught the dosages, the means of administering the DNA, the

actual endpoints to looks for or any experimental data indicating that a method of administering DNA to a subject would indeed prevent or treat a disease associated with transcriptional control. Furthermore, the specification has not taught what form of the DNA is to be administered, does the applicant intend to inject DNA into the blood stream, in the hopes that the DNA will find its way to the site of action? There are specific guidelines for the administration of nucleotides to a subject which involve more than the simple administration of DNA into a subject. Therefore, absent guidance in the form of working examples, the lack knowledge and role of hTFIIIA in diseases associated with transcriptional control, and the unpredictability in the art, one of skill in the art would be forced into undue experimentation to practice the instant invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiwara T *et al* (EP 0704526A1). Claims are drawn to a DNA sequence of hTFIIIA and a method of treating a disease comprising the administration of hTFIIIA DNA, wherein the disease is cancer. Fujiwara T *et al* discloses a hTFIIIA DNA sequence and further teaches that the said DNA can be used for the treatment of disease, wherein the disease is cancer (see page 2 and claims 1-9). Because the patent office does not have the facilities to determine the differences between the nucleotide claimed in the

instant invention and that of the prior art, in the absence of evidence to the contrary, the nucleotide sequences claimed are identical.

Claim Rejections - 35 USC § 102

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Seifart *et al* (J. Biol. Chem. 1989 Jan;263(3):1702-1709). The claim is drawn to a DNA sequence of hTFIIIA. Seifart *et al* disclose the purification of hTFIIIA and further characterize its interaction with a gene encoding 5S rRNA. Because the patent office does not have the facilities to distinguish the differences between the nucleotide claimed in the instant invention and that of the prior art, in the absence of evidence to the contrary, the nucleotide sequences claimed are identical.

Claim Rejections - 35 USC § 102

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Moorefield B *et al* (J. Biol. Chem. 1994 Aug;269(33):20857-20865). The claims is drawn to a DNA sequence of hTFIIIA. Moorefield B *et al* disclose a DNA sequence of hTFIIIA and further point out distinctions between the DNA sequence they isolated from the DNA sequence of the prior art (see above). Because the patent office does not have the facilities to distinguish the differences between the nucleotide claimed in the instant invention and that of the prior art, in the absence of evidence to the contrary, the nucleotide sequences claimed are identical.

Claim Rejections - 35 USC § 102

14. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Arakawa *et al* (Cytogenet Cell Genet 1995;70(3-4):235-8). Claims 1-3 are drawn to a DNA

sequence of hTFIIIA, wherein the DNA sequence is containing a sequence of SEQ ID No: 3. Arakawa *et al* discloses a sequence of hTFIIIA, and further teaches that the sequence is mapped to chromosome 13q12.3. Inherently, that chromosome would contain the same sequence and is therefor anticipated by the human genome. This rejection maybe overcome if the applicant amends the claims to either "comprising" or "consisting" language.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

16. Claims 1-3 and 12-13 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The claims of the instant invention are drawn to a DNA sequence of hTFIIIA. The instant DNA sequence is claimed by another inventor Fujikawa *et al* (EP 0704526A1), wherein the identity between the two sequence is 99.4%. MPEP 2137 states that "Where it can be shown that an applicant "derived" an invention from another, a rejection under 35 U.S.C. 102(f) is proper" (Ex parte Kusko, 215 USPQ 972, 974 (Bd. App.1981)). In the instant case, the instant sequence claimed is "derived" from a published sequence of Fujikawa *et al*. By applicant's own admission, there is only a slight difference between the two sequences (see page 4). Such differences lie in the addition of a single cystine, thereby shifting the reading frame (i.e. "GCG" (Fujikawa *et al*) to "GCCG" (instant application)). Therefore, the instantly claimed sequence is derived from that of Fujikawa *et al*.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
June 2, 2003


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